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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: James et al.

Filed: August 31, 2001

Serial No. 09/914,659

For: Culture of Mycobacteria

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicant wishes to make of record the references listed in the attached Form 1449. Legible copies of all references listed are enclosed.

If any fee is due, the USPTO is authorized to charge Deposit Account No. 08-2442.

Respectfully submitted,

By: Ranjana Kadle
Ranjana Kadle, Reg. No. 40,041

HODGSON RUSS LLP
One M & T Plaza, Suite 2000
Buffalo, New York 14203-2391
Dated: June 16, 2003

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PTO/SB/08B(02/03)

Approved for use through 04/30/2003, OMB 0651-0031

JUN 18 2003

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Application Number	09/914,659
Filing Date	August 31, 2001
First Named Inventor	James et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	18872.0107

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TECH CENTER 1600/2900**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	VAN HEMERT, <i>Vaccine Production as a Unit Process</i> , BCG Vaccine (1971) pp. 110-116	
	2	NYABENDA ET AL., <i>The Production of Mycobacterial Antigens by Homogeneous Culture in a Fermentor</i> , Journal of Biological Standardization (1988) Vol. 16, pp. 259-267	
	3	BLOCH, M.D. ET AL., <i>Variations in Virulence Effected by Tween 80 and Thiosemicarbazone</i> , J. Exp. Med. (1953) Vol. 97, pp. 1-16	
	4	GHEORGHU ET AL., <i>The Stability and Immunogenicity of a Dispersed-Grown Freeze-Dried Pasteur BCG Vaccine</i> , Journal of Biological Standardization (1988) Vol. 16, pp. 15-26	
	5	GHEORGHU ET AL., <i>The Effects of Dispersed or Surface Grown Cultures, Manufacture and Control Methods on BCG Standardization</i> , Develop. Biol. Standard. (1986) Vol. 58, pp. 191-205	
	6	UNGAR, M.D. ET AL., <i>Preparation and Properties of a Freeze-Dried B.C.G. Vaccine of Increased Stability</i> , British Medical Journal (October 27, 1962) pp. 1086-1089	
	7	KIM, <i>High-Viability Lyophilized Bacille Calmette-Guerin Vaccine Produced by Deep-Culture Technique</i> , Appl. and Environ. Microbiol. (1977) Vol. 34, No. 5, pp. 495-499	
	8	DUBOS ET AL., <i>Production of BCG Vaccine in a Liquid Medium Containing Tween 80 and a Soluble Fraction of Heated Human Serum. I. Production and Viability of the Culture.</i> , J. Exp. Med. (1950) Vol. 91, pp. 163-168	
	9	SIRKS ET AL., <i>Production of Freeze-Dried BCG-Vaccine</i> , Symp. Series Immunobiol. Standard. (1971) Vol. 17, pp. 163-168	
	10	FENNER ET AL., <i>Production of BCG Vaccine in a Liquid Medium Containing Tween 80 and a Soluble Fraction of Heated Human Serum. II. Antigenicity of the Culture After Various Periods of Storage.</i> , J. Exp. Med. (1949) Vol. 91, pp. 269-284	
	11	DUBOS ET AL., <i>Media for Tubercle Bacilli</i> , Am. Ref. Tuberc. Pulm. Dis. (1947) Vol. 56, pp. 334-345	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number. ² Applicant is to place a check mark here if English Translation is attached.

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Sheet	2	of	2
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Application Number	09/914,659
Filing Date	August 31, 2001
First Named Inventor	James et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	18872.0105

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
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MASAKI ET AL., *Effect of Tween 80 on the Growth of Mycobacterium Avium*, Complex. Microbiol. Immunol. (1990) Vol. 34, No. 8, pp. 653-663

WARDS, *Evaluation of Defined Media Suitable for Isolation of Auxotrophic Mutants of Mycobacteria*, J. Basic Microbiol. (1996) Vol. 36, pp. 335-362

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